

NOV 24 2004

K042865

Summary of Safety and Effectiveness  
Liquichek Urine Toxicology Control (Levels S1S and S2S)

1.0 **Submitter**

Bio-Rad Laboratories  
9500 Jeronimo Road,  
Irvine, California 92618-2017  
Telephone: (949) 598-1200  
Fax: (949) 598-1555

**Contact Person**

Suzanne S. Parsons  
Regulatory Affairs Specialist  
Telephone: (949) 598-1467

**Date of Summary Preparation**

October 15, 2004

2.0 **Device Identification**

Product Trade Name: Liquichek Urine Toxicology Control (Levels S1S and S2S)  
  
Common Name: Drug Mixture Control  
Classifications: Class I  
Product Code: DIF  
Regulation Number: 21 CFR 862.3280

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Urine Toxicology Control (Levels S1E and S2E)  
Bio-Rad Laboratories  
Irvine, California  
  
Docket Number: K022707

4.0 **Description of Device**

Liquichek Urine Toxicology Controls are prepared from human urine with added drugs of abuse and metabolites of drugs of abuse, preservatives, stabilizers and constituents of animal origin. The control is provided in liquid form for convenience.

5.0 **Statement of Intended Use**

Liquichek Urine Toxicology Control (Levels S1S and S2S) is intended for use as quality controls urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.

## 6.0 Comparison of the new device with the Predicate Device

The new Liquichek Urine Toxicology Controls (Levels S1S and S2S) claims substantial equivalence to the Liquichek Urine Toxicology Controls (Levels S1E and S2E) currently in commercial distribution (K022707).

**Table 1.** Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek Urine Toxicology Control (Levels S1E and S2E) (Predicate Device K022707)	Bio-Rad Liquichek Urine Toxicology Control (Levels S1S and S2S) (New Device)
<b>Similarities</b>		
<b>Intended Use</b>	Liquichek Urine Toxicology Control (Levels S1E and S2E) are intended for use as quality controls urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.	Liquichek Urine Toxicology Control (Levels S1S and S2S) are intended for use as quality controls urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.
<b>Form</b>	Liquid	Liquid
<b>Matrix</b>	Urine	Urine
<b>Storage (Unopened)</b>	2-8°C until expiration date	2-8°C until expiration date
<b>Open Vial</b>	30 days at 2-8°C	30 days at 2-8°C
<b>Differences</b>		
<b>Drugs</b>	<u>Contains:</u> d-Methamphetamine 9-COOH-11-nor-Δ9-THC Benzoylcegonine Morphine (Free) Phencyclidine Secobarbital Lormetazepam Ethanol LSD Methadone Methaqualone Propoxyphene Tricyclic Antidepressants (nortriptyline)  <u>Does not contains</u> 3,4-Methylenedioxymethamphetamine (MDMA)	<u>Contains:</u> d-Methamphetamine 9-COOH-11-nor-Δ9-THC Benzoylcegonine Morphine (Free) Phencyclidine 3,4-Methylenedioxymethamphetamine (MDMA)  <u>Does not contains</u> Secobarbital Lormetazepam Ethanol LSD Methadone Methaqualone Propoxyphene Tricyclic Antidepressants (nortriptyline)

## 7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urine Toxicology Control Levels S1S and S2S. Product claims are as follows:

7.1 Open vial: 30 days at 2-8°C.

7.2 Shelf Life: Three years stored at 2-8 °C

7.3 Real time studies will be ongoing to support the shelf life of this product.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

NOV 24 2004

Ms. Elizabeth Platt  
Regulatory Affairs Manager/ Quality Assurance  
Bio-Rad Laboratories, QSD  
9500 Jeronimo Road  
Irvine, California 92618

Re: k042865  
Trade/Device Name: Liquichek Urine Toxicology Control (Level S1S and S2S)  
Regulation Number: 21 CFR 862.3280  
Regulation Name: Clinical toxicology control material  
Regulatory Class: Class I  
Product Code: DIF  
Dated: October 15, 2004  
Received: October 18, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

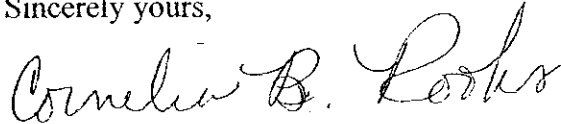
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Cornelia B. Rooks".

Cornelia B. Rooks, MA  
Acting Director  
Division of Chemistry and Toxicology  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: **Liquichek Urine Toxicology Control (Level S1S and S2S)**

Indications For Use: **Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology enzyme immunoassay (EIA) screening procedures.**

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

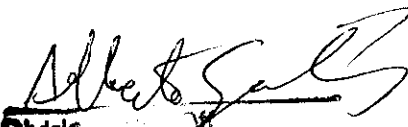
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division of In Vitro Diagnostic Devices

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k)   K042865  

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